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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/592,685	06/12/00	BONADIO J	4100.000582

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EXAMINER	
ROMEO,D	
ART UNIT	**PAPER NUMBER**
1647	4

DATE MAILED: 09/21/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/592,685	Bonadio et al.
Examiner	**Art Unit**
David Romeo	1647

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *12 Jun 2000* .

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *40 and 43-78* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☐ Claim(s) _____ is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☒ Claims *40 and 43-78* are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)

16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____

18) ☐ Interview Summary (PTO-413) Paper No(s). _____

19) ☐ Notice of Informal Patent Application (PTO-152)

20) ☐ Other:

DETAILED ACTION

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 40, 43-45, 75-77, to the extent that they are drawn to a method of a binding TGF-β at a repair site in a mammal with a polypeptide comprising the amino acid sequence of SEQ ID NO: 2, classified in class 514, subclass 12.

II. Claims 40, 43-45, 75, 76, 78, to the extent that they are drawn to a method of a binding TGF-β at a repair site in a mammal with a polypeptide comprising the amino acid sequence of SEQ ID NO: 4, classified in class 514, subclass 12.

III. Claims 40, 43-45, 75-77, to the extent that they are drawn to a method of a binding TGF-β at a bone progenitor tissue site in a mammal with a polypeptide comprising the amino acid sequence of SEQ ID NO: 2, classified in class 514, subclass 12.

IV. Claims 40, 43-45, 75, 76, 78, to the extent that they are drawn to a method of a binding TGF-β at a bone progenitor tissue site in a mammal with a polypeptide comprising the amino acid sequence of SEQ ID NO: 4, classified in class 514, subclass 12.

V. Claims 40, 44, to the extent that they are drawn to in vitro methods of binding TGF-β with a polypeptide comprising the amino acid sequence of SEQ ID NO: 2, classified in class 436, subclass 501.

VI. Claims 40, 44, to the extent that they are drawn to in vitro methods of binding TGF-β with a polypeptide comprising the amino acid sequence of SEQ ID NO: 4, classified in class 436, subclass 501.

VII. Claims 46-50, to the extent that they are drawn to method of immunizing an animal with a polypeptide comprising the amino acid sequence of SEQ ID NO: 2, classified in class 424, subclass 198.1.

VIII. Claims 46-50, to the extent that they are drawn to a method of immunizing an animal with a polypeptide comprising the amino acid sequence of SEQ ID NO: 4, classified in class 424, subclass 198.1.

IX. Claims 46, 51-54, 61-63, 69-73 to the extent that they are drawn to a method of using a polypeptide comprising the amino acid sequence of SEQ ID NO: 2 comprising providing the polypeptide to an animal wherein the polypeptide binds TGF-β and modulates the activation of latent complexes that comprise TGF-β wherein said TGF-β is located within a tissue healing, wound site, classified in class 514, subclass 12.

X. Claims 46, 51-54, 61-63, 69-72, 74 to the extent that they are drawn to a method of using a polypeptide comprising the amino acid sequence of SEQ ID NO: 4 comprising providing the polypeptide to an animal wherein the polypeptide binds TGF-β and modulates the activation of latent complexes that comprise TGF-β wherein said TGF-β is located within a tissue healing, wound site, classified in class 514, subclass 12.

XI. Claims 46, 51-54, 61, 62, 64, 69-73 to the extent that they are drawn to a method of using a polypeptide comprising the amino acid sequence of SEQ ID NO: 2 comprising providing the polypeptide to an animal wherein the polypeptide binds TGF-β and modulates the activation of latent complexes that comprise TGF-β wherein said TGF-β is located within a bone progenitor site, classified in class 514, subclass 12.

XII. Claims 46, 51-54, 61, 62, 64, 69-72, 74, to the extent that they are drawn to a method of using a polypeptide comprising the amino acid sequence of SEQ ID NO: 4 comprising providing the polypeptide to an animal wherein the polypeptide binds TGF-β and modulates the activation of latent complexes that comprise TGF-β wherein said TGF-β is located within a bone progenitor site, classified in class 514, subclass 12.

XIII. Claims 46, 51, 55, 61-63, 69-73 to the extent that they are drawn to a method of using a polypeptide comprising the amino acid sequence of SEQ ID NO: 2 comprising providing the polypeptide to an animal wherein the polypeptide binds TGF-β and targets TGF-β to the extracellular matrix wherein said TGF-β is located within a tissue healing, wound site, classified in class 514, subclass 12.

XIV. Claims 46, 51, 55, 61-63, 69-72, 74 to the extent that they are drawn to a method of using a polypeptide comprising the amino acid sequence of SEQ ID NO: 4 comprising providing the polypeptide to an animal wherein the polypeptide binds TGF-β and targets TGF-β to the extracellular matrix wherein said TGF-β is located within a tissue healing, wound site, classified in class 514, subclass 12.

XV. Claims 46, 51, 55, 61, 62, 64, 69-73, to the extent that they are drawn to a method of using a polypeptide comprising the amino acid sequence of SEQ ID NO: 2 comprising providing the polypeptide to an animal wherein the polypeptide binds TGF-β and targets TGF-β to the extracellular matrix wherein said TGF-β is located within a bone progenitor site, classified in class 514, subclass 12.

XVI. Claims 46, 51, 55, 61, 62, 64, 69-72, 74, to the extent that they are drawn to a method of using a polypeptide comprising the amino acid sequence of SEQ ID NO: 4 comprising providing the polypeptide to an animal wherein the polypeptide

binds TGF-β and targets TGF-β to the extracellular matrix wherein said TGF-β is located within a bone progenitor site, classified in class 514, subclass 12.

XVII. Claims 46, 51, 56, 61-63, 69-73, to the extent that they are drawn to a method of using a polypeptide comprising the amino acid sequence of SEQ ID NO: 2 comprising providing the polypeptide to an animal wherein the polypeptide binds TGF-β and targets TGF-β to the bone matrix wherein said TGF-β is located within a tissue healing, wound site, classified in class 514, subclass 12.

XVIII. Claims 46, 51, 56, 61-63, 69-72, 74, to the extent that they are drawn to a method of using a polypeptide comprising the amino acid sequence of SEQ ID NO: 4 comprising providing the polypeptide to an animal wherein the polypeptide binds TGF-β and targets TGF-β to the bone matrix wherein said TGF-β is located within a tissue healing, wound site, classified in class 514, subclass 12.

XIX. Claims 46, 51, 56, 61, 62, 64, 69-73, to the extent that they are drawn to a method of using a polypeptide comprising the amino acid sequence of SEQ ID NO: 2 comprising providing the polypeptide to an animal wherein the polypeptide binds TGF-β and targets TGF-β to the bone matrix wherein said TGF-β is located within a bone progenitor site, classified in class 514, subclass 12.

XX. Claims 46, 51, 56, 61, 62, 64, 69-72, 74, to the extent that they are drawn to a method of using a polypeptide comprising the amino acid sequence of SEQ ID

NO: 4 comprising providing the polypeptide to an animal wherein the polypeptide binds TGF-β and targets TGF-β to the bone matrix wherein said TGF-β is located within a bone progenitor site, classified in class 514, subclass 12.

XXI. Claims 46, 51, 57, 61-63, 69-73 to the extent that they are drawn to a method of using a polypeptide comprising the amino acid sequence of SEQ ID NO: 2 comprising providing the polypeptide to an animal wherein the polypeptide binds TGF-β and targets TGF-β to connective tissues wherein said TGF-β is located within a tissue healing, wound site, classified in class 514, subclass 12.

XXII. Claims 46, 51, 57, 61-63, 69-72, 74 to the extent that they are drawn to a method of using a polypeptide comprising the amino acid sequence of SEQ ID NO: 4 comprising providing the polypeptide to an animal wherein the polypeptide binds TGF-β and targets TGF-β to connective tissues wherein said TGF-β is located within a tissue healing, wound site, classified in class 514, subclass 12.

XXIII. Claims 46, 51, 57, 61, 62, 64, 69-73 to the extent that they are drawn to a method of using a polypeptide comprising the amino acid sequence of SEQ ID NO: 2 comprising providing the polypeptide to an animal wherein the polypeptide binds TGF-β and targets TGF-β to connective tissues wherein said TGF-β is located within a bone progenitor site, classified in class 514, subclass 12.

XXIV. Claims 46, 51, 57, 61, 62, 64, 69-72, 74 to the extent that they are drawn to a method of using a polypeptide comprising the amino acid sequence of SEQ ID NO: 4 comprising providing the polypeptide to an animal wherein the polypeptide binds TGF-β and targets TGF-β to connective tissues wherein said TGF-β is located within a bone progenitor site, classified in class 514, subclass 12.

XXV. Claims 46, 51, 58, 61-63, 69-73, to the extent that they are drawn to a method of using a polypeptide comprising the amino acid sequence of SEQ ID NO: 2 comprising providing the polypeptide to an animal wherein the polypeptide binds TGF-β and targets TGF-β to the cell surface wherein said TGF-β is located within a tissue healing, wound site, classified in class 514, subclass 12.

XXVI. Claims 46, 51, 58, 61-63, 69-72, 74, to the extent that they are drawn to a method of using a polypeptide comprising the amino acid sequence of SEQ ID NO: 4 comprising providing the polypeptide to an animal wherein the polypeptide binds TGF-β and targets TGF-β to the cell surface wherein said TGF-β is located within a tissue healing, wound site, classified in class 514, subclass 12.

XXVII. Claims 46, 51, 58, 61, 62, 64, 69-73, to the extent that they are drawn to a method of using a polypeptide comprising the amino acid sequence of SEQ

ID NO: 2 comprising providing the polypeptide to an animal wherein the polypeptide binds TGF-β and targets TGF-β to the cell surface wherein said TGF-β is located within a bone progenitor site, classified in class 514, subclass 12.

XXVIII. Claims 46, 51, 58, 61, 62, 64, 69-72, 74, to the extent that they are drawn to a method of using a polypeptide comprising the amino acid sequence of SEQ ID NO: 4 comprising providing the polypeptide to an animal wherein the polypeptide binds TGF-β and targets TGF-β to the cell surface wherein said TGF-β is located within a bone progenitor site, classified in class 514, subclass 12.

XIX. Claims 46, 51, 59, 60-63, 69-73, to the extent that they are drawn to a method of using a polypeptide comprising the amino acid sequence of SEQ ID NO: 2 comprising providing the polypeptide to an animal wherein the polypeptide binds TGF-β and protects TGF-β from proteolytic attack and activation during wound repair or tissue healing, wherein said TGF-β is located within a tissue healing, wound site, classified in class 514, subclass 12.

XXX. Claims 46, 51, 59, 60-63, 69-72, 74, to the extent that they are drawn to a method of using a polypeptide comprising the amino acid sequence of SEQ ID NO: 4 comprising providing the polypeptide to an animal wherein the polypeptide binds

TGF-β and protects TGF-β from proteolytic attack and activation during wound repair or tissue healing, wherein said TGF-β is located within a tissue healing, wound site, classified in class 514, subclass 12.

XXXI. Claims 46, 51, 59, 61, 62, 64, 69-73, to the extent that they are drawn to a method of using a polypeptide comprising the amino acid sequence of SEQ ID NO: 2 comprising providing the polypeptide to an animal wherein the polypeptide binds TGF-β and protects TGF-β from proteolytic attack and activation wherein said TGF-β is located within a bone progenitor site, classified in class 514, subclass 12.

XXXII. Claims 46, 51, 59, 61, 62, 64, 69-72, 74, to the extent that they are drawn to a method of using a polypeptide comprising the amino acid sequence of SEQ ID NO: 4 comprising providing the polypeptide to an animal wherein the polypeptide binds TGF-β and protects TGF-β from proteolytic attack and activation wherein said TGF-β is located within a bone progenitor site, classified in class 514, subclass 12.

XXXIII. Claims 65-68, 76, to the extent that they are drawn to a method of using a polypeptide comprising the amino acid sequence of SEQ ID NO: 2 comprising administering to an animal an amount of a purified polypeptide comprising the amino acid sequence of SEQ ID NO: 2 effective to bind

TGF-β wherein said polypeptide comprising the amino acid sequence of SEQ ID NO: 2 is provided to said animal by contacting a tissue site with a composition comprising a nucleic acid molecule that expresses a polypeptide comprising the amino acid sequence of SEQ ID NO: 2, classified in class 514, subclass 44.

XXXIV. Claims 65-68, 76, to the extent that they are drawn to a method of using a polypeptide comprising the amino acid sequence of SEQ ID NO: 4 comprising administering to an animal an amount of a purified polypeptide comprising the amino acid sequence of SEQ ID NO: 4 effective to bind TGF-β wherein said polypeptide comprising the amino acid sequence of SEQ ID NO: 4 is provided to said animal by contacting a tissue site with a composition comprising a nucleic acid molecule that expresses a polypeptide comprising the amino acid sequence of SEQ ID NO: 4, classified in class 514, subclass 44.

2. The inventions are distinct, each from the other because of the following reasons:

a. The following pairwise combinations of methods are independent and distinct, wherein each member of a pair performs different functions, using different starting materials and/or process steps and/or with different outcomes: I and each of II-XXXIV; II and each of III-XXXIV; III and each of IV-XXXIV; IV and each of V-XXXIV; V and each of VI-XXXIV;

VI and each of VII-XXXIV; VII and each of VIII-XXXIV; VIII and each of IX-XXXIV; IX and each of X-XXXIV; X and each of XI-XXXIV; XI and each of XII-XXXIV; XII and each of XIII-XXXIV; XIII and each of XIV-XXXIV; XIV and each of XV-XXXIV; XV and each of XVI-XXXIV; XVI and each of XVII-XXXIV; XVII and each of XVIII-XXXIV; XVIII and each of XIX-XXXIV; XIX and each of XX-XXXIV; XX and each of XXI-XXXIV; XXI and each of XXII-XXXIV; XXII and each of XXIII-XXXIV; XXIII and each of XXIV-XXXIV; XXIV and each of XXV-XXXIV; XXV and each of XXVI-XXXIV; XXVI and each of XXVII-XXXIV; XXVII and each of XXVIII-XXXIV; XXVIII and each of XXIX-XXXIV; XXIX and each of XXX-XXXIV; XXX and each of XXXI-XXXIV; XXXI and each of XXXII-XXXIV; XXXII and each of XXXIII-XXXIV; XXXIII and each of XXXIV.

3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

4. Because these inventions are distinct for the reasons given above and the searches required are not coextensive, restriction for examination purposes as indicated is proper.

5. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

6. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

ANY INQUIRY CONCERNING THIS COMMUNICATION OR EARLIER COMMUNICATIONS FROM THE EXAMINER SHOULD BE DIRECTED TO DAVID S. ROMEO WHOSE TELEPHONE NUMBER IS (703) 305-4050. THE EXAMINER CAN NORMALLY BE REACHED ON MONDAY THROUGH FRIDAY FROM 7:30 A.M. TO 4:00 P.M.

IF ATTEMPTS TO REACH THE EXAMINER BY TELEPHONE ARE UNSUCCESSFUL, THE EXAMINER'S SUPERVISOR, GARY KUNZ, CAN BE REACHED ON (703) 308-4623.

OFFICIAL PAPERS FILED BY FAX SHOULD BE DIRECTED TO (703) 308-4242.

FAXED DRAFT OR INFORMAL COMMUNICATIONS SHOULD BE DIRECTED TO THE EXAMINER AT (703) 308-0294.

ANY INQUIRY OF A GENERAL NATURE OR RELATING TO THE STATUS OF THIS APPLICATION OR PROCEEDING SHOULD BE DIRECTED TO THE GROUP RECEPTIONIST WHOSE TELEPHONE NUMBER IS (703) 308-0196.

David Romeo

DAVID ROMEO
PRIMARY EXAMINER
ART UNIT 1647

SEPTEMBER 20, 2001